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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,519	09/22/2003	Andre Stamm	31672-224619	5826
26694	7590	11/16/2007		
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998			EXAMINER SHEIKH, HUMERA N	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 11/16/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Advisory Action Before the Filing of an Appeal Brief</p>	<p>Application No. 10/665,519</p>	<p>Applicant(s) STAMM ET AL.</p>	
	<p>Examiner Humera N. Sheikh</p>	<p>Art Unit 1615</p>	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 26 October 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: _____.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's argument that "Boyer does not teach the claimed fenofibrate to polymer ratio of between 1:10 and 4:1", and that "as pointed out by the Office, Boyer teaches 400 kg of fenofibrate and 20 kg of PVP" was not persuasive, since Applicants have not sufficiently demonstrated any unexpected results, which accrue from the instant weight ratio, that results in a patentable distinction over the composition of Boyer. Admittedly, while Boyer uses high drug:polymer ratios, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical (In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955)). In this instance, no criticality has been observed in the instant ratios over the ratios suggested by the prior art. Regarding Applicant's argument that "Boyer uses a very specific process, which involves evaporation of the alcoholic solvent" was not persuasive. Applicant's arguments do not establish the scope of claims being presented. The instant claims are directed to composition claims. Thus, Applicant's argument relating to the use of alcohol solvent by Boyer does not negate the teachings of Boyer over the instant product limitations. Applicant's argument that "a disintegrating agent is absent from Boyer" was not persuasive since Boyer teaches use of a disintegrant, such as starch. See claims 3 & 7. Applicant's arguments relating to the superior dissolution profile as evidenced by the instant Declaration was not persuasive, because dissolution profiles are not being claimed herein. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant's argument that "Curtet does not suggest the claimed fenofibrate to polymer ratio of between 1:10 and 4:1" was not persuasive, since as noted above, no unexpected results have been demonstrated using the instant drug:polymer ratio. Applicant argues that "Curtet do not teach the presence of both a hydrophilic polymer and a disintegrant" was not persuasive. Note for instance, column 3, Table 1, lines 20-32, whereby Curtet discloses a fenofibrate preparation comprising both a hydrophilic polymer (polyvinylpyrrolidone) and disintegrant (starch). Thus, this argument was not persuasive. With regards to the Blouquin Declaration, the Declaration presents dissolution profiles, which are not being claimed. Further, for reasons advanced in the Final Office Action, Applicant's arguments were not persuasive.


HUMERA N SHEIKH
PRIMARY EXAMINER